

K213827 TITAN Total Shoulder System (TSS), TITAN Reverse Shoulder System (RSS), TITAN Humeral Resurfacing Arthroplasty System (HRA), Modular Radial Head System (MRH), Katalyst Bipolar Radial Head System (Katalyst)Mar 11, 2022
93 days to decisionK213827 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k213827/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Dec 8, 2021
Decision date	Mar 11, 2022
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew, Inc.
Location	McHenry, IL, US
Contact	Stephanie Rincones
Website	http://www.smith-nephew.com/
510(k) history	530 submissions · 517 cleared · 1980-2026

Smith & Nephew, Inc. is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in McHenry, US. Smith & Nephew has established a significant regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since 1980. Orthopedic devices represent the dominant category, accounting for 71% of submissions. The company remains active, with the latest clearance in 2025. Recent cleared devices reflect a strong focus on orthopedic surgical...